

NCHHSTP Human Subjects Research Routing Determination

This form should be used to submit to NCHHSTP ADS materials for projects and activities involving CDC investigations that do not require routing to the CDC Human Research Protection Office. Projects are eligible for this classification either as "non human subjects research" projects (primary intent is not to generate generalizable knowledge), as research projects that do not involve identifiable human subjects, or as research projects in which CDC is not "engaged". Such projects do not require submission to the CDC Human Research Protection Office (HRPO) for human subjects research review. Do **NOT** use this form for "exempt" research that must be routed to HRPO.

Project Title: Population-based surveillance of high-grade cervical intraepithelial neoplasia (CIN) and HPV type to monitor HPV vaccine impact

Project Locations/Sites: California (Alameda County), Connecticut (New Haven County), New York (Monroe County), Tennessee (Davidson County)

Project Officer(s) Susan Hariri, PhD MPH Division: DSTDP Telephone: 404-639-2046

Proposed Project Dates: Start: 01 / 01 / 2008 End: ongoing

Categories of data collection that do not constitute human subjects research are listed below. Please check appropriate category:

- I. Activity is not human subjects research.** Primary intent is public health practice or a disease control activity.
- A. Epidemic or endemic disease control activity; collected data directly relate to disease control needs.
 - B. Routine disease surveillance activity; data used for disease control program or policy purposes.**
 - C. Program evaluation activity; data are used primarily for that purpose.
 - D. Post-marketing surveillance of efficacy or adverse effects of a new regimen, drug, vaccine, or device.
- II. Activity is not human subjects research.** Primary intent is public health program activities.
(Category II may be determined by Division ADS)
- A. Public health program activity (including service delivery, health education, social marketing campaigns, program monitoring and process measures, and risk reduction interventions).
 - B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment) and not related to research
- III. Activity is research but does NOT involve identifiable human subjects.**
- A. Activity is research involving collection or analysis of data about health facilities or other organizations or units which are not individual persons...**OR**...
 - B. Activity is research involving data or specimens from deceased persons...**OR**...
 - C. Activity is research using unlinked anonymous data or specimens: **ALL** (1-4) of the following are required:
 - 1. No contact with human subjects is involved for the proposed activity...**and**...
 - 2. Data or specimens are/were collected for another purpose...**and**...
 - 3. No extra data/specimens are/were collected for **this** purpose...**and**...
 - 4. Identifying information either was not obtained **or** has been removed so that data cannot be linked or re-linked with identifiable human subjects. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCHSTP ADS office for details.)
- IV. Activity is research involving identifiable human subjects but CDC involvement does not constitute "engagement in the research".** **ALL** (A-C) of the following are required:
- A. This project is conducted under a grant or cooperative agreement award mechanism.
 - B. CDC employees or agents do not intervene or interact with living individuals for research purposes.
 - C. CDC employees or agents do not obtain individually identifiable private information.

Supported Institution/Entity Name _____
Supported Institution/Entity FWA # _____ Expiration Date _____
Local IRB # _____ IRB Approval Expiration Date _____

Attach project description (standard format at end of this form) in enough detail to justify the proposed category. Submit through division ADS/Director to: nchstphs@cdc.gov

Check here if this request is an amendment of an existing determination of human subjects research review routing.

Approval initials: [Signature] Branch or Section Chief [Signature] Date [Signature] ADS or Div. Director [Signature] Date

Project Title Population-based surveillance of high-grade cervical intraepithelial neoplasia (CIN) and HPV type to monitor HPV vaccine impact

NCHSTP ADS Review

Date received in NCHSTP ADS Office: Oct 26.07

Concur, project does not require human research review beyond NCHHSTP


or

Project constitutes human subjects research that must be routed to CDC HRPO

Comments/Rationale:

Additional Comments:

1. This form cannot be used to document human subjects research that is exempt from human subjects regulations; such research must instead be submitted to the CDC HRPO. (Please contact the NCHSTP ADS Office for details).
2. Although CDC HRPO review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality, and autonomy of participants. All applicable State and Federal privacy laws must be followed.
3. Although this project does not require routing to CDC HRPO, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements as adapted to the project.
4. Other:

Signed: 
Salaam Semaan, DrPH
~~Acting~~ Associate Director for Science, NCHHSTP
National Center for HIV, Viral Hepatitis, STD, and TB Prevention

Oct 30.07
Date